

# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Addiese: COMMISSIONER FOR PATENTS PO Box 1450 Alexandra, Virginia 22313-1450 www.wepto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,665	10/11/2005	Martin G. Reese	22966-81050	2598
33:04. 75:0 03/25/2008 SIDLEY AUSTIN LLP ATTN: DC PATENT DOCKETING			EXAMINER	
			SMITH, CAROLYN L	
1501 K STREET, N.W. WASHINGTON, DC 20005			ART UNIT	PAPER NUMBER
			1631	
			MAIL DATE	DELIVERY MODE
			03/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/552.665 REESE ET AL. Office Action Summary Examiner Art Unit Carolyn L. Smith 1631 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-26 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) \_\_\_\_\_ is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-26 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

PTOL-326 (Rev. 08-06)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/S5/08)
Paper No(s)/Mail Date \_\_\_\_\_\_.

Attachment(s)

Interview Summary (PTO-413)
Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

Application/Control Number: 10/552,665 Page 2

Art Unit: 1631

#### DETAILED ACTION

This application has been filed under 35 U.S.C. § 371 and has been determined to have Lack of Unity of invention under PCT Rule 13.1 and under 37 CFR § 1.499 regarding the U.S. National Stage application as summarized below:

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-21 and 24-25, drawn to a method for determining whether an individual has an enhanced, diminished, or average probability of exhibiting one or more phenotypic attributes, classified in class 702, subclass 19. If this group is elected then SEVEN specie election requirements are also required as summarized below.

Group II, claim(s) 22, drawn to a method of evaluating the probability that progeny of two individuals of the opposite sex will exhibit one or more phenotypic attributes, classified in class 703, subclass 2.

Group III, claim(s) 23, drawn to a method for determining the genomic ethnicity of an individual, classified in class 703, subclass 11.

Application/Control Number: 10/552,665

Art Unit: 1631

Group IV, claim(s) 26, drawn to a method of selecting a set of genetic markers, classified in class 707, subclass 7.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Each group is directed to a different special technical feature and contains different goals, method steps (where applicable), and/or structure/function (where applicable). Group I is directed to a method for determining whether an individual has an enhanced, diminished, or average probability of exhibiting one or more phenotypic attributes. Group II is directed to a method of evaluating the probability that progeny of two individuals of the opposite sex will exhibit one or more phenotypic attribures. Group III is directed to a method for determining genomic ethnicity. Group IV is directed to a method of selecting a set of genetic markers.

Clearly, each Group contains its own special technical feature which supports the lack of unity present in this application.

### Species Election Requirements for Group I:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

First specie election requirement:

Specie A: preselected set of markers that comprises a plurality of exon/intron junction sequences

Specie B: preselected set of markers that comprises a plurality of promoter sequences

Second specie election requirement:

Specie C: selecting preselected set of markers by prioritizing by nucleotide sequence

homology

Specie D: selecting preselected set of markers by prioritizing by synteny with respect to

other marker sequences

Specie E: selecting preselected set of markers by prioritizing by ontological relevance

Specie F: selecting preselected set of markers by prioritizing by genomic relevance

Specie G: selecting preselected set of markers by prioritizing by quality of supporting

research

Specie H: selecting preselected set of markers by prioritizing by degree of phenotypic

significance

Third Specie election requirement:

Specie I: scoring matrix that prioritizes markers with respect to homology to another

marker sequence

Specie J: scoring matrix that prioritizes markers with respect to synteny to other marker

sequences

Specie K: scoring matrix that prioritizes markers with respect to ontological relevance

Specie L: scoring matrix that prioritizes markers with respect to genomic relevance

Specie M: scoring matrix that prioritizes markers with respect to quality of supporting

research

Fourth Specie election requirement:

Group I contains patently distinct species, namely scoring matrix vectors. If Group I is elected, please select one scoring matrix vector (i.e. from claim 11), so that examination of this

application may proceed.

Fifth Specie election requirement:

Specie N: selection criteria that is a function of the availability of treatments effective to

modify the phenotypic characteristic

Specie O: selection criteria that is a function of the scope and quality of known research

relating to the phenotypic characteristic

Specie P: selection criteria that is a function of the probability determination(s) for one

or more other phenotypic characteristics

Sixth Specie election requirement:

Specie Q: organizational matrix that groups phenotypic characteristics for which the

individual has an enhanced probability together

Specie R: organizational matrix that groups phenotypic characteristics related to similar

physiological systems together

Seventh Specie election requirement:

Specie S: organization matrix that ranks the phenotypic characteristics as a function of

the potential impact on the individual's lifestyle or quality of life

Specie T: organization matrix that ranks the phenotypic characteristics as a function of

the genomic ethnicity of an individual

Applicant is required, in reply to this action, to elect a single species to which the claims

shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

the claims readable on the elected species, including any claims subsequently added. An

argument that a claim is allowable or that all claims are generic is considered non-responsive

unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of

claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP

§ 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT

Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special

technical features for the following reasons:

In the first species election requirement, the special technical feature of Specie A includes a plurality of exon/intron sequences which differs from the other special technical feature. In the first species election requirement, the special technical feature of Specie B includes a plurality of promoter sequences which differs from the other special technical feature.

In the second specie election requirement, the special technical feature of Specie C is nucleotide sequence homology which differs from the other special technical features. In the second specie election requirement, the special technical feature of Specie D is synteny with respect to other marker sequences which differs from the other special technical features. In the second specie election requirement, the special technical feature of Specie E is ontological relevance which differs from the other special technical features. In the second specie election requirement, the special technical feature of Specie F is genomic relevance which differs from the other special technical features. In the second specie election requirement, the special technical feature of Specie G is quality of supporting research which differs from the other special technical features. In the second specie election requirement, the special technical feature of Specie H is degree of phenotypic significance which differs from the other special technical features.

In the third specie election requirement, the special technical feature of Specie I is homology to another marker sequence which differs from the other special technical features. In the third specie election requirement, the special technical feature of Specie J is synteny to other marker sequences which differs from the other special technical features. In the third specie election requirement, the special technical feature of Specie K is ontological relevance which differs from the other special technical features. In the third specie election requirement, the

Application/Control Number: 10/552,665

Art Unit: 1631

special technical feature of Specie L is genomic relevance which differs from the other special technical features. In the third specie election requirement, the special technical feature of Specie M is quality of supporting research which differs from the other special technical features.

In the fourth specie election requirement, the special technical features include different scoring matrix vectors that differ from each other.

In the fifth specie election requirement, the special technical feature of Specie N is the availability of treatments effective to modify the phenotypic characteristic which differs from the other special technical features. In the fifth specie election requirement, the special technical feature of Specie O is the scope and quality of known research relating to the phenotypic characteristic which differs from the other special technical features. In the fifth specie election requirement, the special technical feature of Specie P is the probability determination(s) for one or more other phenotypic characteristics which differs from the other special technical features.

In the sixth specie election requirement, the special technical feature of Specie Q is grouping phenotypic characteristics for which the individual has an enhanced probability together which differs from the other special technical feature. In the sixth specie election requirement, the special technical feature of Specie R is grouping related to similar physiological systems together which differs from the other special technical feature.

In the seventh specie election requirement, the special technical feature of Specie S is the potential impact on the individual's lifestyle or quality of life which differs from the other special technical feature. In the seventh specie election requirement, the special technical feature of Specie T is the genomic ethnicity of an individual which differs from the other special technical feature.

Application/Control Number: 10/552,665

Art Unit: 1631

These different special technical features document the lack of unity among the species for each particular specie election requirement.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Application/Control Number: 10/552,665 Page 10

Art Unit: 1631

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

March 7, 2008

/Carolyn Smith/ Primary Examiner AU 1631

# Application Number